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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/088,248 | 07/24/2002 | Jens Schletter | 50125/051001 | 9271 |

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| EXAMINER | |
|---|---|
| NGUYEN, DAVE TRONG | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/088,248 | SCHLETTER, JENS | |
| | Examiner | Art Unit | |
| | Dave T Nguyen | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 28-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 28-76 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 28, 53, 55, 65, 66, 67, drawn a pharmaceutical composition, and a method of using the composition for treating a vascular disorder, wherein the therapeutic DNA codes for an unspecified protein, classifiable in class 424, subclass 450, or class 514, subclass 44;

II. Claim 28, 53, 55, 65, drawn to a pharmaceutical composition, and a method of using the composition for treating a genetically related disorder, wherein the therapeutic DNA codes for an unspecified protein which corrects the disorder, classifiable in class 424, subclass 450, or class 514, subclass 44;

III. Claims 74-76, drawn to a method of stabilizing nucleic acid/lipid complexes during lyophilization and/or reconstitution, comprising the use of an isoosmotic composition, classifiable in class 435, subclass 320.1, and 455.

Should Group I, II, or III be elected, a further group restriction is required:

I)i) Applicant is required to elect a particular invention regarding a specifically named vascular disorder as listed in claim 57 and claim 67.

Claims 28, 47, 54, 55, 64-66, for example, are identified as the linking claims.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III, and more specifically invention I(i), drawn to a particular named therapeutic DNA, is directed to a distinct pharmaceutical or gene therapy DNA, which by itself is composed of a particular structure and function required for a pharmaceutical effect as claimed in each of the respective group. Given an enormous number of therapeutic DNA as broadly claimed, and a required distinct functional effect, depending

on the targeted disease disorder, let alone the therapeutic and/or preventive goal, an undue burden is required to search and examine anything more than of the above groups and subgroups.

Should any of the above group and a subsequent subgroup be elected, a Species Restriction is required under 35 U.S.C. 121:

The presently pending claims are generic to a plurality of disclosed patentably distinct species comprising:

A) A particular species of a cationic lipid chosen from the group as listed in claim 34, for example;

B) A particular species of a non-cationic lipid chosen from the list as set forth in claim 35, for example; Further, should phosphatidylethanoamine be elected, a further species of phosphatidylethanoamine must be elected from the group as listed in claim 37; and

C) A particular species of stabilizing agent chosen from the list as set forth in claim 45 or 51, for example;

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from A), B), and C) as indicated above, even though this requirement is traversed. Each of the listed species is structurally distinct, and thereby resulting in an specific functional effect, which may not be overlapped in prior art search and examination. Thus, a search and examination of anything more than one of such together for patentablility would be unduly burdensome to the examiner.

Should applicant traverse on the ground that the species are not patentably

distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine for patentability of all of the claimed inventions, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER